

4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2019-F-3519]

Kellogg Company; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Kellogg Company, proposing that the food additive regulations be amended to provide for the safe use of vitamin D<sub>3</sub> as a nutrient supplement in breakfast cereals and in grain-based nutrition bars (e.g., granola bars).

DATES: The food additive petition was filed on June 25, 2019.

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lane A. Highbarger, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1204.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), we are giving notice that we have filed a food additive petition (FAP 9A4823), submitted on behalf of Kellogg Company by Hogan Lovells US LLP,

Columbia Square, 555 Thirteenth Street, NW, Washington, DC 20004. The petition proposes to

amend the food additive regulations in § 172.380 (21 CFR 172.380; Vitamin D<sub>3</sub>) to provide for

the safe use of vitamin D<sub>3</sub> as a nutrient supplement as defined in § 170.3(o)(20) (21 CFR

170.3(o)(20)) in breakfast cereals as defined in § 170.3(n)(4) and in grain-based nutrition bars

(e.g., granola bars) and to update the specifications for vitamin D<sub>3</sub> established in § 172.380(b) by

incorporating by reference the most recent edition of the Food Chemicals Codex.

We have determined under 21 CFR 25.32(k) that this action is of a type that does not

individually or cumulatively have a significant effect on the human environment. Therefore,

neither an environmental assessment nor an environmental impact statement is required.

Dated: August 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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